REMARKS

A. Status of the Claims

Claims 1-17, 19, and 22-27 were pending in the case at the time of the Office Action, with claims 2-4, 6, 10-12, and 14 having been previously withdrawn from consideration. Claims 13, 25, and 26 been amended in the Amendment set forth herein. Claim 27 has been canceled without prejudice or disclaimer. Support for the amendments of the claims can be found generally throughout the specification, such as in the claims as originally filed and on page 1, line 14 of the disclosure. Thus, claims 1, 5, 7-9, 13, 15-17, 19, and 22-26 are currently under consideration.

B. Amendment of Claims

In the Amendment set forth herein, claim 13 has been amended to omit the phrase "and the MUC1 test agent is phosphorylated." In accordance with 37 C.F.R. §1.116(b)(1)-(2), Applicant respectfully requests entry of the amendment of the claims. The amendment addresses two rejections as discussed in greater detail below.

C. The Objections to the Claims Are Overcome

Claims 13 and 26 have been objected to for certain informalities. Claim 13 has been objected to for reciting that the MUC1 test agent is phosphorylated. Claim 1, from which claim 13 depends, recites that the MUC1 test agent is phosphorylated at the YEKV site. Claim 13 has been amended to omit "and the MUC1 test agent is phosphorylated" since claim 1 recites that the MUC1 test agent is phosphorylated at the YEKV site. Further, claim 26 was objected to for including a misspelling. Applicant has corrected the misspelling. Therefore, the objections to the claims have been overcome.

D. The Indefiniteness Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome

Claim 13 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting that the MUC1 test agent is phosphorylated. As discussed above, claim 13 has been amended to omit this limitation since claim 1, from which claim 13 depends, recites that the MUC1 test agent is phosphorylated at the YEKV site. Therefore, Applicant respectfully requests withdrawal of this rejection.

E. The Rejections Under 35 U.S.C. §112, First Paragraph, Are Moot

Claims 25-26 are rejected under 35 U.S.C. §112, first paragraph, because the specification is said to not be enabling for methods that involve sources of phosphate ions other than ATP. Applicant notes that claim 25 has been amended to recite the limitation of claim 27 (which recites ATP as the source of phosphate ions). Claim 27 has been canceled without prejudice or disclaimer. Claim 26 depends from claim 25. Therefore, the rejection of claims 25 and 26 is moot.

F. The Rejections Under 35 U.S.C. §103(a) Are Overcome

Claims 1, 5, 7-9, 13, 15-17, and 22-27 are rejected under 35 U.S.C. §103(a) as being unpatentable over Li *et al.* (Mol. Cell Biol. 18(12):7216-7224, 1998; of record in IDS; hereinafter "Li-1") in view of Yamamoto *et al.* (J. Biol. Chem. 272(19):12492-12494, 1997; of record; hereinafter "Yamamoto") and Barker *et al.* (U.S. Patent 5,891,775; hereinafter "Barker"), as evidenced by Li *et al.* (J. Biol. Chem. 276(38):35239-35242, 2001; of record in IDS; hereinafter "Li-2") and Zrihan-Licht *et al.* (FEBS Letters 356(1):130-136, 1994; hereinafter "Zrihan-Licht"). The Examiner cites Li-1 and Yamamoto as providing methods of identifying a compound that inhibits binding of the β-catenin tumor progressor to a MUC1 test site. Barker is said to provide motivation for the use of a peptide fragment of β-catenin, and Zrihan-Licht is said

to teach that the MUC1 test agent will necessarily be phosphorylated at the YEKV site. Applicant respectfully traverses.

In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A finding of obviousness requires that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103(a). In setting forth a *prima facie* case of obviousness, it is necessary to show "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In the present case, there is *no prima* facie case of obviousness for the following reasons:

Li-1 teaches that glycogen synthase kinase 3β binds to an STDRSPYE site in MUC1 and phosphorylates the serine that is adjacent to a proline. This phosphorylation decreases the binding of MUC1 to β-catenin. Li-1 does not teach or suggest that phosphorylation of a YEKV site increases binding of MUC1 to β-catenin. The Examiner has cited to FIG. 5 of Li-1 as teaching GSK3β as the test agent. However, there is no information in Li-1 to teach or suggest that the MUC1 test agent equivalent in Li-1 was phosphorylated at a YEKV site. Nor would this be inherent, as it is possible for a YEKV site to not be phosphorylated, and Li-1 teaches that it is phosphorylation of a serine residue that affects interaction of MUC1 with β-catenin.

Yamamoto does not provide any teaching or suggestion concerning a MUC1 test agent phosphorylated at a YEKV site. Rather, it concerns certain studies demonstrating that DF3

(MUC1) binds directly to β-catenin and that the SXXXXXSSL motif in DF3 is responsible for this interaction.

Further, as admitted by the Examiner, neither Li-1 nor Yamamoto teach that the β-catenin test agent is a peptide fragment. Barker is cited as teaching that certain assays may be conducted utilizing a β-catenin fragment that is shorter than the full-length tumor progressor. It is not cited as providing any teaching or suggestion concerning assays concerning any MUC1 test agent that is phosphorylated at a YEKV site. The Examiner admits that neither Li-1, Yamamoto, nor Barker teach that the MUC1 test agent includes a phosphorylated YEKV site. *See* Office Action, page 9.

The Examiner adds Li-2 and Zrihan-Licht as allegedly providing for MUC1 test agents that are phosphorylated at a YEKV site. Applicant has herein submitted the Declaration of Dr. Kufe under 37 C.F.R. §1.132 establishing that Li-2 is Applicant's own work, and, being published less than one year prior to the instant application is not prior art against the present application. *MPEP* §715.01(c), citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). While Zrihan-Licht discloses that MUC1 proteins are "extensively phosphorylated" and that phosphorylation occurs "primarily on tyrosine residues" it does not specifically teach phosphorylation of the YEKV site of MUC1. Abstract. MUC1 protein includes 13 tyrosine residues, and there is no information in this reference or in any of the other references to suggest that this particular tyrosine residue, out of all of the amino acids of MUC1, is critical for binding to β-catenin. Further, Zrihan-Licht teaches that other residues may undergo phosphorylation, including serine residues. P. 131, right col., third para. Still further, Zrihan-Licht teaches that the sequence YEEV is important for interaction with SH2 domain-containing tyrosine kinases, thus teaching away from the importance of a YEKV site. In addition, one of ordinary skill in

the art would further be led away from the importance of phosphorylation of a YEKV site because, as discussed above, Li-1 teaches that it is a serine residue that affects interaction of MUC1 with β-catenin and Yamamoto teaches that the SXXXXXSSL motif in DF3 is responsible for this interaction.

In view of the foregoing, it is respectfully submitted that there is no *prima facie* case of obviousness based on the combination of references cited by the Examiner. There is no rational reason that would have led one of ordinary skill in the art, at the time of the invention, to determine that the YEKV site of MUC1 is critical for binding to β-catenin.

Therefore, Applicant respectfully requests that the rejection of claims 1, 5, 7-9, 13, 15-17, and 22-27 under 35 U.S.C. §103(a) be withdrawn.

It is noted that claim 19 was not included in this rejection and should be considered allowable even if the Examiner chooses to maintain the rejection of the claims under 35 U.S.C. §103(a).

G. The Double Patenting Rejections Are Overcome

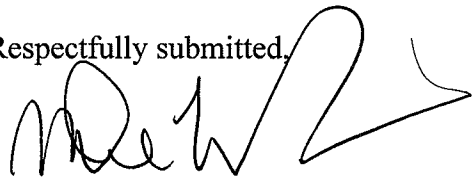
Claims 1, 5, 7-9, 13, and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 7-8 of copending Application No. 10/032,786 (U.S. 2002/0110841 A1). Without conceding that the claims at issue are not patentably distinct from the claims of the '786 application, Applicant will address this issue by filing a terminal disclaimer (concurrently filed herewith).

H. Conclusion

Applicant believes that the foregoing comments are a complete response to the pending Office Action, and a Notice of Allowance is earnestly solicited. The Examiner is invited to

contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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